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PATENT

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May 3, 2005
Date

Jason Anover

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Thomas D. Madden et al.
Application No. : 09/896,811
Filed : June 29, 2001
For : LIPOSOMAL CAMPTOTHECINS AND USES THEREOF

Examiner : Frederick F. Krass
Art Unit : 1614
Docket No. : 480208.407
Date : May 3, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 CFR 1.56 and 1.97 through 1.98, applicants wish to make known to the U.S. Patent and Trademark Office the references set forth on the attached Form PTO-1449. Copies of the cited U.S. patents and published patent applications are not required and accordingly have not been provided. Copies of all other cited references are enclosed. As to any reference cited, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 CFR 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they

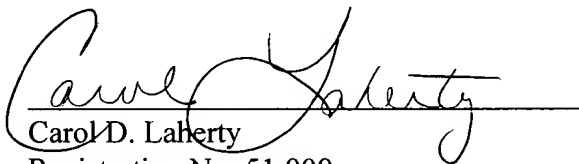
are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Supplemental Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Supplemental Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC


Carol D. Laherty
Registration No. 51,909

Enclosures:

Postcard
Form PTO-1449
Cited References (124)

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TRANSMITTAL FORM

(To be used for all correspondence
after initial filing)

Application Number	09/896,811
Filing Date	June 29, 2001
First Named Inventor	Thomas D. Madden
Art Unit	1614
Examiner Name	Frederick F. Krass
Attorney Docket No.	480208.407

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Request for Corrected Filing Receipt	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Response	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to TC (<i>Appeal Notice, Brief, Reply Brief</i>)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address	<input checked="" type="checkbox"/> Return Receipt Postcard
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Declaration	<input type="checkbox"/> Other Enclosure(s) (<i>please identify below</i>):
<input checked="" type="checkbox"/> Information Disclosure Statement; Form PTO-1449	<input type="checkbox"/> Statement under 37 CFR 3.73(b)	
<input checked="" type="checkbox"/> Cited References	<input type="checkbox"/> Terminal Disclaimer	
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<input type="checkbox"/> Response to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Seed Intellectual Property Law Group PLLC	Customer Number	00500
Signature			
Printed Name	Carol D. Laherty		
Date	May 3, 2005	Reg. No.	51,909

CERTIFICATE OF TRANSMISSION/MAILING

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Typed or printed name	Jason Añover	Date:	May 3, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FORM PTO-1449
(REV. 7-80)

MAY 05 2005

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

480208.407

APPLICATION NO.

09/896,811

APPLICANTS

Thomas D. Madden et al.

FILING DATE

June 29, 2001

GROUP ART UNIT

1614

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA						

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
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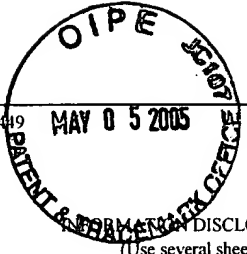
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AC	Abraham, S. A., K. Edwards, et al. "An evaluation of transmembrane ion gradient-mediated encapsulation of topotecan within liposomes." <i>J Control Release</i> 96(3): 449-61, 2004.
AD	Apostolidou, E., G. Garcia-Manero, et al. "Phase I Study of OSI-211, a Novel Liposomal Topoisomerase 1 (Topo 1) Inhibitor, in Patients with Refractory Leukemia." <i>Blood</i> , 2002. Abstract #4575.
AE	Biloti, D. N., A. Santana Maria Helena, et al. "Lipid membrane with low proton permeability." <i>Biochim Biophys Acta</i> 1611(1-2): 1-4, 2003.
AF	Bom, D., D. P. Curran, et al. "The novel silatecan 7-tert-butyldimethylsilyl-10-hydroxycamptothecin displays high lipophilicity, improved human blood stability, and potent anticancer activity." <i>J Med Chem</i> 43(21): 3970-80, 2000.
AG	Bom, D., D. P. Curran, et al. "The highly lipophilic DNA topoisomerase I inhibitor DB-67 displays elevated lactone levels in human blood and potent anticancer activity." <i>J Control Release</i> 74(1-3): 325-33, 2001.
AH	Burke, T. G. and D. Bom, "Camptothecin design and delivery approaches for elevating anti-topoisomerase I activities in vivo." <i>Ann N Y Acad Sci</i> 922: 36-45, 2000.
AI	Burke, T. G. and X. Gao "Stabilization of topotecan in low pH liposomes composed of distearoylphosphatidylcholine." <i>J Pharm Sci</i> 83(7): 967-9, July 1994.
AJ	Burke, T. G., E. Staibus Alfred, et al. "Liposomal stabilization of Camptothecin lactone ring." <i>J Am Chem Soc</i> 114:8318-8319, 1992.
AK	Burke, T. G., Z. Mi, et al. "Liposomal stabilization of camptothecins." <i>Proc Amer Assoc Cancer Res.</i> 35:416, March 1994. Abstract #2479
AL	Chou, T.-H., S.-C. Chen, et al. "Effect of composition on the stability of liposomal irinotecan prepared by a pH gradient method." <i>Journal of Bioscience and Bioengineering.</i> 95(4):405-408, 2003
AM	Chow, D. S. L., G. Chen, et al. "Liposomal camptothecin and 9-nitro-camptothecin: Formulation, pharmacokinetics and preclinical anti-tumor activity." <i>Proceedings of the Controlled Release Society</i> , pp. 919-920, 1997.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 480208.407	APPLICATION NO. 09/896,811
			APPLICANTS Thomas D. Madden et al.	
			FILING DATE June 29, 2001	GROUP ART UNIT 1614

DISCLOSURE STATEMENT
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

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BA						

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
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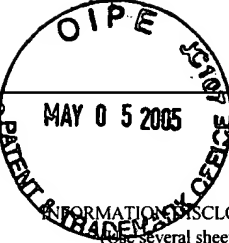
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BC	Chow, D. S., L. Gong, et al. "Modified lactone/carboxylate salt equilibria in vivo by liposomal delivery of 9-nitro-camptothecin." <i>Ann N Y Acad Sci</i> 922:164-74, 2000.
BD	Clements, M. K., C. B. Jones, et al. "Antiangiogenic potential of camptothecin and topotecan." <i>Cancer Chemother Pharmacol</i> 44(5): 411-6, 1999.
BE	Clements, M. K., S. Wasi, et al. "Camptothecin exhibits selective cytotoxicity towards human breast carcinoma as compared to normal bovine endothelial cells in vitro." <i>Anticancer Drugs</i> 7(8): 851-7, 1996.
BF	Colbern, G. T., D. J. Dykes, et al. "Encapsulation of the topoisomerase I inhibitor GL147211C in pegylated (STEALTH) liposomes: pharmacokinetics and antitumor activity in HT29 colon tumor xenografts." <i>Clin Cancer Res</i> 4(12): 3077-82, December 1998.
BG	Daoud, S. S., M. I. Fetouh, et al. "Antitumor effect of liposome-incorporated camptothecin in human malignant xenografts." <i>Anticancer Drugs</i> 6(1): 83-93, 1995.
BH	Dunton, C. J. "New options for the treatment of advanced ovarian cancer." <i>Semin Oncol</i> 24(1 Suppl 5):S5-2-S5-11, February 1997.
BI	El-Kareh, A. W. and T. W. Secomb "Theoretical models for drug delivery to solid tumors." <i>Crit Rev Biomed Eng</i> 25(6): 503-571, 1997.
BJ	Emerson, D. L. "Liposomal delivery of camptothecins." <i>Pharmaceutical Science and Technology Today</i> 3(6): 205-209, June 2000.
BK	Emerson, D. L., N. Amirgahari, et al. "NX-211, a liposomal formulation of lurtotecan demonstrates enhanced pharmacokinetic and antitumor activity." <i>Proc Amer Assoc Cancer Res</i> 39: 278, March 1998. Abstract #1897.
BL	Emerson, D. L., R. Bendele, et al. "Antitumor efficacy, pharmacokinetics, and biodistribution of NX 211: a low-clearance liposomal formulation of lurtotecan." <i>Clin Cancer Res</i> 6(7): 2903-12, July 2000.
BM	Emerson, D., A. Gray, et al. "The topoisomerase I inhibitor, NX211 demonstrates significant in vivo activity against human acute myeloid leukemia (AML) engrafted in SCID mice." <i>Blood</i> , 1999. Abstract #4223.

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FORM PTO-1449 (REV. 7-80)		MAY 0 5 2005		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 480208.407		APPLICATION NO. 09/896,811	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)						APPLICANTS Thomas D. Madden et al.			
						FILING DATE June 29, 2001		GROUP ART UNIT 1614	
U.S. PATENT DOCUMENTS									
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	CA								
FOREIGN PATENT DOCUMENTS									
		DOCUMENT NUMBER	DATE	COUNTRY			TRANSLATION		
							YES NO		
	CB								
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)									
	CC	Erickson-Miller, C. L., R. D. May, et al. "Differential toxicity of camptothecin, topotecan and 9-aminocamptothecin to human, canine, and murine myeloid progenitors (CFU-GM) in vitro." <i>Cancer Chemother Pharmacol</i> 39(5): 467-72, 1997.							
	CD	Garcia-Carbonero, R. and J.G. Supko "Current perspectives on the clinical experience, pharmacology, and continued development of the camptothecins." <i>Clin Cancer Res</i> 8(3): 641-661, March 2002.							
	CE	Gelmon, K., H. Hirte, et al. "A phase 1 study of OSI-211 given as an intravenous infusion days 1, 2, and 3 every three weeks in patients with solid cancers." <i>Invest New Drugs</i> 22(3): 263-75, 2004.							
	CF	Giles, F. J., M. S. Tallman, et al. "Phase I and pharmacokinetic study of a low-clearance, unilamellar liposomal formulation of lurtotecan, a topoisomerase 1 inhibitor, in patients with advanced leukemia." <i>Cancer</i> 100(7): 1449-58, April 2004.							
	CG	Giles, F., M. Tallman, et al. "Phase I and pharmacokinetic study of OSI-211, a liposomal formulation of lurtotecan, a topoisomerase 1 inhibitor, in patients with advanced leukemia." <i>Blood</i> , p. 2516, 2003. Abstract #4732.							
	CH	Guo, W., A. Ahmad, et al. "Determination by liquid chromatography with fluorescence detection of total 7-ethyl-10-hydroxy-camptothecin (SN-38) in beagle dog plasma after intravenous administration of liposome-based SN-38 (LE-SN38)." <i>J Chromatogr B</i> 791(1-2): 85-92, 2003.							
	CI	Hatefi, A. and B. Amsden "Camptothecin delivery methods." <i>Pharm Res</i> 19(10):1389-1399, October 2002.							
	CJ	Khan, S., A. Ahmad, et al. "A sensitive and rapid liquid chromatography tandem mass spectrometry method for quantitative determination of 7-ethyl-10-hydroxycamptothecin (SN-38) in human plasma containing liposome-based SN-38 (LE-SN38)." <i>Biomedical chromatography - BMC</i> 17(8): 493-9, 2003.							
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

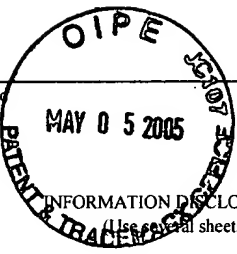
	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
DB					

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

DC	Knight, V., E. S. Kleinerman, et al. "9-Nitrocamptothecin liposome aerosol treatment of human cancer subcutaneous xenografts and pulmonary cancer metastases in mice." <i>Ann N Y Acad Sci</i> 922: 151-63, 2000.
DD	Knight, V., N. Koshkina, et al. "Anti-cancer activity of 9-nitrocamptothecin liposome aerosol in mice." <i>Trans Am Clin Climatol Assoc</i> 111: 135-45, 2000.
DE	Knight, V., N. V. Koshkina, et al. "Anticancer effect of 9-nitrocamptothecin liposome aerosol on human cancer xenografts in nude mice." <i>Cancer Chemother Pharmacol</i> 44(3): 177-86, 1999.
DF	Koshkina, N. V., B. E. Gilbert, et al. "Distribution of camptothecin after delivery as a liposome aerosol or following intramuscular injection in mice." <i>Cancer Chemother Pharmacol</i> 44(3): 187-92, 1999.
DG	Koshkina, N. V., E. S. Kleinerman, et al. "9-Nitrocamptothecin liposome aerosol treatment of melanoma and osteosarcoma lung metastases in mice." <i>Clin Cancer Res</i> 6(7): 2876-80, 2000.
DH	Koshkina, N. V., V. Knight, et al. "Improved respiratory delivery of the anticancer drugs, camptothecin and paclitaxel, with 5% CO ₂ -enriched air: pharmacokinetic studies." <i>Cancer Chemother Pharmacol</i> 47(5): 451-6, 2001.
DI	Lei, S., P.-Y. Chien, et al. "Enhanced therapeutic efficacy of a novel liposome-based formulation of SN-38 against human tumor models in SCID mice." <i>Anticancer Drugs</i> 15(8): 773-8, 2004.
DJ	Liu, J. J., R. L. Hong, et al. "Simple and efficient liposomal encapsulation of topotecan by ammonium sulfate gradient: stability, pharmacokinetic and therapeutic evaluation." <i>Anticancer Drugs</i> 13(7): 709-17, 2002.
DK	Liu, X., B. C. Lynn, et al. "A versatile prodrug approach for liposomal core-loading of water-insoluble camptothecin anticancer drugs." <i>J Am Chem Soc</i> 124(26): 7650-1, 2002.

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U.S. PATENT DOCUMENTS

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EA						

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				YES	NO
EB					

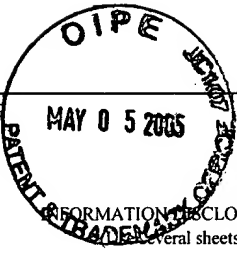
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EC	Loos, W. J., D. Kehrler, et al. "Liposomal lurtotecan (NX211): determination of total drug levels in human plasma and urine by reversed-phase high-performance liquid chromatography." <i>J Chromatogr B</i> 738(1): 155-63, 2000.
ED	Loos, W. J., J. Verweij, et al. "Structural identification and biological activity of 7-methyl-10,11-ethylenedioxy-20(S)-camptothecin, a photodegradant of lurtotecan." <i>Clin Cancer Res</i> 8(3): 856-62, March 2002.
EE	Lundberg, B. B. "Biologically active camptothecin derivatives for incorporation into liposome bilayers and lipid emulsions." <i>Anticancer Drug Des</i> 13(5): 453-61, 1998.
EF	Luo, J. D., Z. Q. Ma, et al. "[Studies on polyphase liposome of camptothecin, PL-CSA]." <i>Yao xue xue bao = Acta pharmaceutica Sinica</i> 19(1): 63-8, 1984.
EG	Lynam, E., D. J. Landfair, et al. "Camptothecin analogue efficacy in vitro: Effect of liposomal encapsulation of GI147211C (NX211)." <i>Drug Delivery: Journal of Delivery and Targeting of Therapeutic Agents</i> 6:51-62, 1999.
EH	MacKenzie, M. J., H. W. Hirte, et al. "A phase I study of OSI-211 and cisplatin as intravenous infusions given on days 1, 2 and 3 every 3 weeks in patients with solid cancers." <i>Ann Oncol</i> 15(4): 665-70, 2004.
EI	Maliepaard, M., M. A. Van Gastelen, et al. "Circumvention of breast cancer resistance protein (BCRP)-mediated resistance to camptothecins in vitro using non-substrate drugs or the BCRP inhibitor GF120918." <i>Clin Cancer Res</i> 7(4): 935-941, April 2001.
EJ	Meerum, T. J. M., J. H. M. Schellens, et al. "Clinical pharmacology of anticancer agents in relation to formulations and administration routes." <i>Cancer Treat Rev</i> 25(2): 83-101, 1999.
EK	Messerer, C. L., E. C. Ramsay, et al. "Liposomal irinotecan: formulation development and therapeutic assessment in murine xenograft models of colorectal cancer." <i>Clin Cancer Res</i> 10(19): 6638-49, October 2004.
EL	Mi, Z. and T. G. Burke "Differential interactions of camptothecin lactone and carboxylate forms with human blood components." <i>Biochemistry</i> 33(34): 10325-36, 1994.

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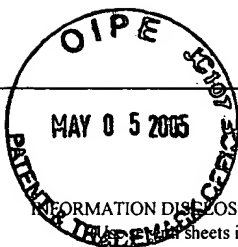
	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
FB					

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

FC	Proulx, M. E., A. Desormeaux, et al. "Treatment of visceral leishmaniasis with sterically stabilized liposomes containing camptothecin." <i>Antimicrob Agents Chemother</i> 45(9): 2623-7, 2001.
FD	Proulx, M. E., J. F. Marquis, et al. "Incorporation of camptothecin into liposomes: A new approach for the treatment of leishmaniasis." <i>Abstracts of the 39th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy</i> , San Francisco, 1999. Abstract 1856.
FE	Sadzuka, Y. "Effective prodrug liposome and conversion to active metabolite." <i>Curr Drug Metab</i> 1(1): 31-48, 2000.
FF	Sadzuka, Y., S. Hirotsu, et al. "The study of polyethyleneglycol-coated liposomes containing CPT-11." <i>J Liposome Res</i> 7(2&3): 241-260, 1997.
FG	Sadzuka, Y., S. Hirotsu, et al. "Effect of liposomalization on the antitumor activity, side-effects and tissue distribution of CPT-11." <i>Cancer Lett</i> 127(1-2): 99-106, 1998.
FH	Sadzuka, Y., S. Hirotsu, et al. "Effective irinotecan (CPT-11)-containing liposomes: intraliposomal conversion to the active metabolite SN-38." <i>Jpn J Cancer Res</i> 90(2): 226-32, February 1999.
FI	Seiden, M. V., F. Muggia, et al. "A phase II study of liposomal lurtotecan (OSI-211) in patients with topotecan resistant ovarian cancer." <i>Gynecol Oncol</i> 93(1): 229-32, 2004.
FI	Stano, P., S. Bufali, et al. "Novel camptothecin analogue (gimatecan)-containing liposomes prepared by the ethanol injection method." <i>J Liposome Res</i> 14(1-2): 87-109, 2004.
FK	Subramanian, D. and M. T. Muller "Liposomal encapsulation increases the activity of the topoisomerase I inhibitor topotecan." <i>Oncol Res</i> 7(9): 461-9, 1995.
FL	Tardi, P., E. Choice, et al. "Liposomal encapsulation of topotecan enhances anticancer efficacy in murine and human xenograft models." <i>Cancer Res</i> 60(13): 3389-93, July 2000.
FM	Tomkinson, B. E., E. Brown, et al. "In vivo evaluation of NX 211 in combination with cisplatin, 5-FU, and paclitaxel." <i>Proc Amer Assoc Cancer Res</i> 41:144, March 2000. Abstract #917.

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GB					


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GC	Tomkinson, B., R. Bendele, et al. "OSI-211, a novel liposomal topoisomerase I inhibitor, is active in SCID mouse models of human AML and ALL." <i>Leukemia Research</i> 27(11): 1039-50, 2003.
GD	Verschraegen, C. F., B. E. Gilbert, et al. "Feasibility, phase I, and pharmacological study of aerosolized liposomal 9-nitro-20(S)-camptothecin in patients with advanced malignancies in the lungs." <i>Ann N Y Acad Sci</i> 922: 352-4, 2000.
GE	Verschraegen, C. F., B. E. Gilbert, et al. "Clinical evaluation of the delivery and safety of aerosolized liposomal 9-nitro-20(s)-camptothecin in patients with advanced pulmonary malignancies." <i>Clin Cancer Res</i> 10(7): 2319-26, April 2004.
GF	Verschraegen, C. F., K. Jaeckle, et al. "Alternative administration of camptothecin analogues." <i>Ann N Y Acad Sci</i> 922: 237-46, 2000. Abstract only
GG	Zhang, J. A., T. Xuan, et al. "Development and characterization of a novel liposome-based formulation of SN-38." <i>Int J Pharm</i> 270(1-2): 93-107, 2004.
GH	Zhang, Q. M., X. Q. Gu, et al. "[A method for determining the encapsulation ratio of camptothecin in polyphase liposome and studies on its leakage property]." <i>Yao xue xue bao = Acta Pharmaceutica Sinica</i> 22(12): 918-22, 1987.
GI	Zufia, L., A. Aldaz, et al. "Separation methods for camptothecin and related compounds." <i>J Chromatogr B</i> 764(1-2): 141-159, 2001.
GJ	Zunino, F., S. Dallavalle, et al. "Current status and perspectives in the development of camptothecins." <i>Curr Pharm Des</i> 8(27): 2505-2520, 2002.
GK	Desjardins, J. P., E. A. Abbott, et al. (2001). "Biodistribution of NX211, liposomal lurtotecan, in tumor-bearing mice." <i>Anticancer Drugs</i> 12(3): 235-45, March 2001.
GL	Begu, S., C. Tourne-Peteilh, et al. "Spectrofluorimetry study of interaction of camptothecin with liposomal bilayer." <i>Luminescence</i> 15:78-79, 2000.
GM	Bell, C. B., D. J. Landfair, et al. "Topoisomerase I (TOPO-1) modulation by liposomal GI147211 (NX211)." <i>Proc Amer Assoc Cancer Res</i> 41, p. 773, March 2000. Abstract #4915.

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 480208.407	APPLICATION NO. 09/896,811
			APPLICANTS Thomas D. Madden et al.	
			FILING DATE June 29, 2001	GROUP ART UNIT 1614

U.S. PATENT DOCUMENTS

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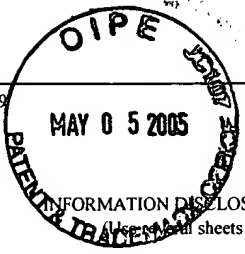
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HB	Bevins, R. L., D. Bom, et al. "Tumor cell cycle disruption and apoptosis induced by DB-67, a highly lipophilic camptothecin displaying improved human blood stability." <i>Proc Amer Assoc Cancer Res</i> 42, p. 102, March 2001. Abstract #554.
HC	Bom, D. C., J. Zhang, et al. "The structural basis of camptothecin loading and retention in liposomal drug carriers." <i>Proc Amer Assoc Cancer Res</i> 42:374, March 2001. Abstract #2016.
HD	Burke, T. G., A. J. Chavan, et al. "Development and evaluation of a liposomal formulation of highly lipophilic 7-t-butyldimethylsilyl-10-hydroxy-camptothecin." <i>Proc Amer Assoc Cancer Res</i> 40, March 1999. Abstract #752.
HE	Burke, T. G., D. Subramanian, et al. "Enhanced bloodstream stability and in vitro activity of topotecan formulated in liposomes." <i>Pharm Res</i> 11(10):S-323, October 1994. Abstract # PDD 7596.
HF	Burke, T. G., S. Gao Xiang, et al. "Liposomal stabilization of the lactone ring of camptothecin anticancer drugs." <i>Pharm Res</i> 10(10):S-220, October 1993. Abstract # PDD 7483.
HG	Burke, T. G., X. Liu, et al. "A versatile pro-drug approach for the liposomal core loading of camptothecin anticancer drugs." <i>Proc Amer Assoc Cancer Res</i> 43, March 2002. Abstract #5731.
HH	Burke, T. G., Z. Mi, et al. (1994). "Liposomal formulations of camptothecins for cancer treatment." Abstracts of Papers American Chemical Society, In <i>Proceedings of the 208th ACS National Meeting</i> , Washington, DC, August 21-25, 1994. Abstract #50
HI	Cao, Z. and C. Giovannella Beppino, "Liposomal prodrugs comprising derivatives of camptothecin and methods of treating cancer using these prodrugs." <i>Official Gazette of the United States Patent and Trademark Office Patents</i> 1256(1):372, March 2002. US Patent 6,352,996 B1.
HJ	Chavan, A. J., K. A. Fraley, et al. "A comparative study of the human blood stability characteristics of remote-loaded liposomal carriers containing clinically-relevant camptothecins." <i>Proc Amer Assoc Cancer Res</i> 40:417, March 1999. Abstract #6019.
HK	Chen, G., A. Double John, et al. "Characterization of liposomal mimetic formulations for selective targeting." <i>Pharm Res</i> 13:S-161, September 1996. Abstract # PPDM 8345.
HL	Chen, G., W. Barry Brian, et al. "Pharmacokinetic evaluation of liposomal camptothecin." <i>Pharm Res</i> 13(9):S-479, September 1996.

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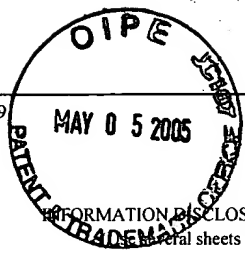
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	IC	Cherian, M. "Lyophilizate of lipid complex of water insoluble camptothecins." <i>Official Gazette of the United States Patent and Trademark Office Patents</i> 1269(3), April 2003. U.S. Patent 6,548,071 B1.
	ID	Chien, P.-Y., S. Sheikh, et al. "Cytotoxicity evaluation of a liposome-based formulation of SN38 in human and murine cancer cell lines." <i>Proc Amer Assoc Cancer Res</i> 44:314, July 2003. Abstract #1607.
	IE	Choice, E., M. B. Bally, et al. "Delivery of topotecan using liposomes: Drug loading into liposomes and drug and carrier pharmacokinetics in female Balb/c mice." <i>Proc Amer Assoc Cancer Res</i> 40, March 1999. Abstract #753.
	IF	Chow, D. S. L., G. Chen, et al. "Pharmacokinetics and in vivo antitumor activity of liposomal encapsulated camptothecin and its analog." <i>Proc Amer Assoc Cancer Res</i> 38, March 1997.
	IG	Cortesi, R., E. Esposito, et al. "Formulation study for the antitumor drug camptothecin: Liposomes, micellar solutions and a microemulsion." <i>Int J Pharm</i> 159:95-103, 1997.
	IH	Cortesi, R., E. Esposito, et al. "Liposomes, micelles and microemulsions as new delivery systems for camptothecin." <i>Eur J Pharm Sci</i> 6(Supp. 1):S3, 1998. Abstract #12
	II	Dallavalle, S., L. Merlini, et al. "Perspectives in camptothecin development." <i>Expert Opinion on Therapeutic Patents</i> 12(6):837-844, 2002.
	IJ	Daoud, S. S., M. I. Fetouh, et al. (1993). "Multilamellar liposomes as a delivery system for camptothecin (NSC 94600) and 9-aminocamptothecin (NSC 603071)." in <i>Proc Amer Assoc Cancer Res</i> . Orlando, FL, May 19-22, 1993, 367. Abstract #2188
	IK	Desjardins, J. P., D. L. Emerson, et al. "Biodistribution of NX 211, liposomal GI147211, in tumor bearing mice." <i>Proc Amer Assoc Cancer Res</i> 41:702, March 2000. Abstract #4467.
	IL	Emerson, D. L., N. Amirghahari, et al. "Enhanced in vivo antitumor efficacy of the liposome formulated topoisomerase I inhibitor Lurtotecan." <i>Proc Amer Assoc Cancer Res</i> 40:113, March 1999. Abstract #751
	IM	Emerson, D. L., R. Bendele, et al. "In vivo antitumor efficacy of liposomal lurtotecan (NX 211) in human xenografts." <i>Proc Amer Assoc Cancer Res</i> 42:100, March 2001. Abstract #545.

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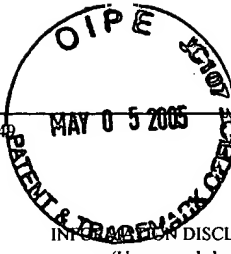
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JD		Gilbert, B. E., A. Seryshev, et al. "9-nitrocamptothecin liposome aerosol: lack of subacute toxicity in dogs." <i>Inhal Toxicol</i> 14(2): 185-97, 2002.
JE		Gong, L., B. C. Giovanella, et al. "Improved lactone stability of 9-nitro-camptothecin in vitro and in vivo by liposomal formulation." <i>Proc Amer Assoc Cancer Res</i> 39:430, March 1998. Abstract #2926
JF		Gong, L., B. C. Giovanella, et al. "Sustained organ exposure to 9-nitro-camptothecin (9NC) lactone form by liposomal delivery." <i>Proc Amer Assoc Cancer Res</i> 40:417, March 1999. Abstract #2756.
JG		Gong, L., G. Chen, et al. "Development and characterization of liposomal formulation of 9-nitro-camptothecin." <i>Pharm Res</i> 13:S-162, September 1996. Abstract #6021.
JH		Haas, H., B. Schulze, et al. "Strong antitumor efficacy of a cationic liposomal camptothecin formulation (LipoCam TM) in the subcutaneous human melanoma A-375 in nude mice." <i>Proc Amer Assoc Cancer Res</i> 44:350-351, July 2003. Abstract # R1793.
JI		Kamath, N., K. Sarkar Asis, et al. "Therapeutic efficacy of liposome-based formulation of SN38 against leukemia model in CD2F1 mice." <i>Proc Amer Assoc Cancer Res</i> 44, 2 nd Ed., July 2003. Abstract #1784.
JJ		Khan, S., S. Ali, et al. "Liposome based formulation of SN-38 (LE-SN38): A four-cycle toxicity evaluation in beagle dogs." <i>Toxicological Sciences</i> 72(S-1), March 2003. Abstract #1873.
JK		Knight, J. V., B. Gilbert, et al. "Small particle liposome aerosols for delivery of anti-cancer drugs." <i>Official Gazette of the United States Patent and Trademark Office Patents</i> 1236(3):2973, July 18, 2000. U.S. Patent 6,090,407.
JL		Koshkina, N. V., B. E. Gilbert, et al. (1999). "Pharmacokinetics and tissue distribution of camptothecin after delivery as a liposome aerosol or following intramuscular injection in mice." <i>Proc Amer Assoc Cancer Res</i> 40:10, March 1999. Abstract #734.

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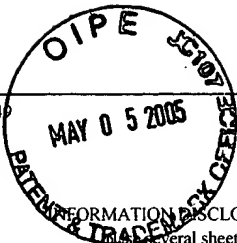
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KC	Kruszewski, S., A. S. Chavan, et al. (2000). "Comparison of the human blood chemistry of free versus liposomal forms of the clinically-relevant topoisomerase I inhibitor Lurtotecan (GI147221)." <i>Proc Amer Assoc Cancer Res</i> 41:324, March 2000. Abstract #2056.
KD	Lerchen, H. G. "Camptothecin antitumor agents." <i>Idrugs</i> 2(9):896-906, 1999.
KE	Loos, W. J., D. F. S. Kehrer, et al. "Clinical pharmacodynamics of liposomal lurtotecan (NX 211): Urinary excretion predicts hematologic toxicity." <i>Proc Amer Assoc Cancer Res</i> 42:102, March 2001. Abstract #551.
KF	Lopez-Barcons, L. A., J. Zhang, et al. "The novel highly lipophilic topoisomerase I inhibitor DB67 is effective in the treatment of liver metastases of murine CT-26 colorectal carcinoma." <i>Proc Amer Assoc Cancer Res</i> 44(2): 348, 2003. Abstract #1782.
KG	Lynam, E., D. J. Landfair, et al. "Camptothecin analogue efficacy in vitro: Effect of liposomal encapsulated of GI147211C (Lurtotecan) on vitro cytotoxicity for multiple tumor cell types." <i>Proc Amer Assoc Cancer Res</i> 31:421, March 1998.
KH	Mamot, C., D. C. Drummond, et al. "Liposome-based approaches to overcome anticancer drug resistance." <i>Drug Resistance Updates</i> 6:271-279, 2003.
KI	Michaelis, U., B. Schulze, et al. "Cationic liposomes (Catioms) to target tumor neovasculature." Abstracts of Papers American Chemical Society, in <i>Proceedings of the 226th ASC National Meeting</i> , New York, September 7-11, 2003.
KJ	Moynihan Karen, L., L. Emerson David, et al. "Liposomal camptothecin formulations." <i>Official Gazette of the United States Patent and Trademark Office Patents</i> , 2004. U.S. Patent 6,740,335B1.
KK	Pal, A., S. Sheikh, et al. "Enhanced antitumor efficacy of liposome-based formulation of SN38 against human pancreatic tumor in SCID mice." <i>Proc Amer Assoc Cancer Res</i> , 2003. Abstract #1785.
KL	Poirot, K., Y. Zou, et al. "Liposomal-camptothecin composed of cationic phospholipids containing unsaturated fatty acids: Formulation and cytotoxicity studies." <i>Proc Amer Assoc Cancer Res</i> 37:300, March 1996. Abstract #2039.
KM	Sadzuka, Y., S. Hirotsu, et al. "Antitumor effect of CPT-11 encapsulated liposome and conversion to active metabolite." <i>J Liposome Res</i> , pp. 101-102, 1998.

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FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
				YES NO
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LC	Sarkar, A., N. Kamath, et al. "Toxicity evaluation of a liposome-based formulation of SN38 in mice." <i>Toxicol Sci</i> 72(S-1):83, March 2003. Abstract #403.
LD	Semple, S. C., B. L. S. Mui, et al. "Comparative efficacy and therapeutic index of topotecan and liposomal topotecan in murine and human solid tumor models." <i>Proc Amer Assoc Cancer Res</i> 44, July 2003. Abstract #3658.
LE	Semple, S. C., S. K. Klimuk, et al. "Pre-clinical evaluation of liposomal topotecan: Increased efficacy and therapeutic index in murine and human xenograft tumor models compared to free drug." <i>Proc Amer Assoc Cancer Res</i> 42:374, March 2001. Abstract #2015.
LF	Sugarman, S. and R. Perez-Soler "Liposomal camptothecin: Formulation and cytotoxicity against KB cells." <i>Proc Amer Assoc Cancer Res</i> , Orlando, FL, May 19-22, 1993, p. 422. Abstract #2519.
LG	Tanyeli, C., D. Bom, et al. "Formulation and pharmacological characterization of the novel polyamine camptothecin CT-17 encapsulated in low-clearance liposomes." <i>Proc Amer Assoc Cancer Res</i> 42:255, March 2001. Abstract #1379.
LH	Tomkinson, B., E. Brown, et al. (2001). "Efficacy of NX 211 in SCID mouse models of human leukemia." <i>Proc Amer Assoc Cancer Res</i> 42:100, 2001. Abstract #542.
LI	Ulukan, H., D. Roy, et al. "Controlled release of topotecan from thermosensitive liposomes." <i>Proc Amer Assoc Cancer Res</i> 36:308, March 1995. Abstract #1833.
LJ	Yu, N. Y., C. Conway, et al. "STEALTH liposome formulation enhances antitumor efficacy of CKD-602, a topoisomerase I inhibitor, in human tumor xenograft models." <i>Proc Amer Assoc Cancer Res</i> 45: 710, March 2004. Abstract #3069.
LK	Zunino, F. and G. Pratesi "Camptothecins in clinical development." <i>Expert Opin Investig Drugs</i> 13(3): 269-284, 2004.
LL	Madden T. et al., "Encapsulation of Topotecan in Lipid-Based Carrier Systems: Evaluation of Drug Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L1210 and B16", <i>Proceedings from 34th Annual ASCO Meeting</i> , 1998. Abstract #754.

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